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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,378	03/24/2006	Kenya Shitara	00005.01290	4546
5514 7590 08/20/2008 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				
EXAMINER				
DANG, IAN D				
ART UNIT		PAPER NUMBER		
1647				
MAIL DATE		DELIVERY MODE		
08/20/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/573,378

**Applicant(s)**

SHITARA ET AL.

**Examiner**

IAN DANG

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 17-21, 25-28 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 17-21 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 30 January 2008 has been entered in full. Claims 2-16, 22-24, 29, and 30 have been cancelled and claims 1, 17-21, and 25-28 have been amended. Claim 31 has been added. Claims 25-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 17-21, and 31 are under examination.

### ***Specification***

Applicants have updated the status of the parent applications in the first line of the specification in the amendments filed on 01/30/2008. However, the disclosure remains objected to because of the following new informalities: the specification does not properly label the figures. For instance, page 112, line 12, Fig. 3 should be replaced with Fig. 3A-B. The same objection applies for Figure 4-6, 9, 10, and 12.

Appropriate correction is required.

### **Rejections Withdrawn**

#### ***35 USC § 112, Second paragraph***

Applicant's response, arguments, and amendments made to claim 1 filed on 01/30/2008 have overcome the rejection of claims 1-13, 20-21, 29-30 under 35 USC 112, Second paragraph. The rejection regarding "at the same degree", "biological activities", and "represented by" of claims 1-13, 20-21, 29-30 under 35 USC 112, Second paragraph has been withdrawn.

***35 USC § 112, First paragraph (Enablement)***

Applicant's response, arguments, and amendments made to claim 1 filed on 01/30/2008 have overcome the rejection of claims 1-7, 9-13, 20, and 21 under 35 USC 112, First paragraph (Enablement). The rejection of claims 1-7, 9-13, 20, and 21 under 35 USC 112, First paragraph (Enablement) has been withdrawn.

***Double Patenting***

Applicant's response, arguments, and amendments made to claim 1 filed on 01/30/2008 have overcome the rejection of claims 1-8, 20, 21, and 29, and 30 under Double Patenting. The copending Application No. 10/513,148 do not recite the amino acid sequences SEQ ID NO:26 for VH and the amino acid sequences SEQ ID NO:27-29 for VL. The rejection of claims 1-8, 20, 21, 29, and 30 under Double Patenting has been withdrawn.

***35 USC § 102***

Applicant's response and arguments filed on 01/30/2008 have overcome the rejection of claims 1 and 2 under 35 USC 102(b). The reference by Ben et al. does not teach the VH of amino acid sequence consisting of SEQ ID NO:26 and the VL of amino acid sequence of SEQ ID NO:27, 28, or 29. The rejection of claims 1 and 2 under 35 USC 102(b) have been withdrawn.

**New Grounds of Rejection**

***Claim Rejections - 35 USC § 112 (New Matter)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 17-21, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection. The newly added limitation reciting "can bind to both human IGF-I and human IGF-II with equivalent strength affinity" represents a departure from originally filed. Although Applicant has pointed out the location for the support for the newly added limitation of claim 1 in the specification, the Examiner has determined that the specification provides insufficient support for the amendments made to claim 1. For instance, the specification teaches that the KA of the anti-hIGF antibody KM1468 to hIGF-I was  $7.86 \times 10^9 \text{ M}^{-1}$ , and the KA to hIGF-II was  $8.63 \times 10^9 \text{ M}^{-1}$ . Since the KA ratio of KM1468 to hIGF-I and hIGF-II was almost 1:1, it was shown that KM1468 can bind strongly to both of hIGF-I and hIGF-II with an almost the same degree (page 93, lines 1-3). However, the specification does not provide adequate support for the limitations reciting "can bind to both human IGF-I and human IGF-II with equivalent strength affinity." The limitations are not expressly asserted, nor do they flow naturally from the specification.

***Claim Rejections - 35 USC § 112, Second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 17-21, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "activity" in claim 1 is a relative term which renders claim 1 indefinite. The term "activity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For instance, it is not clear as to what is the nature of the activity is required to control the proliferation, differentiation or apoptosis of epithelial cells. Without the knowledge regarding the claimed activity, the examiner has been unable to determine the metes and bound of the claim.

Claim 1 is indefinite because the elements recited in the claim do not constitute proper Markush groups. The claims are indefinite in the alternative use of "and/or" because it is not clear what controls which of these limitations. (See especially claim 1.) See MPEP § 2173.05(h).

**Conclusion**

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### **Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
August 12, 2008

/Robert Landsman/  
Primary Examiner, Art Unit 1647